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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/804,760
Filing Date: March 19, 2004
Appellant(s): SACKS ET AL.

Alan G. Towner
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 3/1/2010 appealing from the Office action mailed 3/31/2009.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The Examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

4472387	Laruelle et al.	9-18-1984
5470846	Sandyk	11-28-1995

6264994 Castillo et al. 7-24-2001

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 112 (New Matter)

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1 and 4-10 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant adds new limitations to the claims that raise the issue of new matter. New matter issues are raised when Applicant includes limitations in the claims that he/she clearly did not have possession of at the time of invention. The silence of the disclosure regarding **consisting essentially of** is not sufficient to now claim the exclusion of such steps because nowhere in the disclosure has Applicant discussed **consisting essentially of** in the context of the claimed method.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1 and 4-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Laruelle et al. (US Pat. No. 4472387) in view of Sandyk (US Pat. No. 5470846) and further in view of Castillo et al. (US Pat. No. 6264994 B1).

Laruelle et al. disclose a pharmaceutical composition suitable for increasing cerebral serotonin concentration, comprising a serotonin precursor and inosine and hypoxanthine (see abstract). Treatment consists of administering to a mammal having

a lower than normal cerebral serotonin level an amount of a pharmaceutical composition of the present invention effective to increase the cerebral serotonin level. Daily dosages of 1 to 100 mg/kg are preferred (see col. 5, lines 8-22).

Sandyk teaches a method of treating neurological and mental disorders which are associated with and/or related pathogenetically to deficient serotonin neurotransmission (see abstract). Treatment of neurological and mental disorders which are associated with pathogenetically to deficient serotonin are Alzheimer's disease and Parkinson's disease. Neurological and mental disorders are treated by administering to such humans in need thereof an effective amount of a composition which increases serotonin transmission (col. 7, lines 44-50).

Castillo et al. teach that the invention relates to compositions and methods for treating Alzheimer's Disease and other amyloidoses and cognitive and mental effects thereof; more particularly, it relates to herbal compositions for intervention in Alzheimer's disease and other amyloidoses and for remedies to cognitive and mental effects thereof (col. 1, lines 12-17). The pharmaceutical agent is selected from polyphenols and plants sterols (see col. 8, lines 13-16). Castillo et al. further discloses that the composition of the invention will have enhanced function when function when taken together with one or more of the following antioxidants such as vitamin C or vitamin E (see col. 19, lines 62-65).

One skilled in the art would have been motivated to combine the teachings of the above references considering that it is generally prima facie obvious to combine two or more compositions each of which is taught by the prior art to be useful for the same

purpose, in order to form a composition which is to be used for the very same purpose. The idea for combining them flows logically from their having been used individually in the prior art. As shown by the recited teachings, the instant claims define nothing more than the concomitant use of serotonin, inosine, hypoxanthine, and antioxidants to increase the uptake of serotonin in treating Alzheimer's disease. It would follow that the recited claims define prima facie obvious subject matter. In re Kerhoven, 626 F.2d 848, 205 USPQ 1069 (CCPA 1980).

It would have been obvious to have combined the teachings of the above references to formulate a method of treating Alzheimers' patients by increasing the serotonin composition uptake along with antioxidants such as polyphenols and Vitamin C.

Finally, one would have a reasonable expectation of success given that Laruelle et al., Sandyk, and Castillo et al. provide a detailed blueprint for treatment of Alzheimers' patients, and the steps of which are routine to one of ordinary skill in the art.

The transitional phrase "consisting essentially of" limits the scope of a claim to the specified materials or steps "and those that do not materially affect the basic and novel characteristic(s)" of the claimed invention. In re Herz, 537 F.2d 549, 551-52, 190 USPQ 461, 463 (CCPA 1976). "A consisting essentially of' claim occupies a middle ground between closed claims that are written in a consisting of' format and fully open claims that are drafted in a comprising' format." PPG Industries v. Guardian Industries, 156 F.3d 1351, 1354, 48 USPQ2d 1351, 1353-54 (Fed. Cir. 1998). See also Atlas Powder v. E.I. duPont de Nemours & Co., 750 F.2d 1569, 224 USPQ 409 (Fed. Cir.

1984); In re Janakirama-Rao, 317 F.2d 951, 137 USPQ 893 (CCPA 1963); Water Technologies Corp. vs. Calco, Ltd., 850 F.2d 660, 7 USPQ2d 1097 (Fed. Cir. 1988). For art purposes, “the consisting essentially of” language in the claim is treated as “comprising” language and it is an applicant's burden to establish that a step practiced in a prior art method is excluded from his claims by consisting essentially of' language.” (See MPEP 2111.03)

Thus in the absence of evidence to the contrary, the invention of claims 1 and 4-10 would have been prima facie obvious as a whole to one of ordinary skill in the art at the time the invention was made.

(10) Response to Argument

Appellants argue none of the cited references disclose the instant claimed invention. Appellants traverse this rejection by indicating claim 1 clearly recites that the daily dosage consists essentially of a specified amount of hypoxanthine, xanthine and/or inosine. The claimed method includes administering the claimed daily dosage composition to a patient. The phrase "consisting essentially of" does not modify any "step" recited in the claim, but rather modifies the "daily dosage" by restricting its composition to the recited amounts of hypoxanthine, xanthine and/or inosine, as well as any other additional ingrediems that would not affect the basic and novel characteristics of the composition. The disclosure fully supports the claimed daily dosage composition and its administration to patients. Accordingly, the 35 U.S.C. § 112(1) rejection should be reversed.

Appellants arguments are not persuasive The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant adds new limitations to the claims that raise the issue of new matter. New matter issues are raised when Applicant includes limitations in the claims that he/she clearly did not have possession of at the time of invention. The silence of the disclosure regarding **consisting essentially of** is not sufficient to now claim the exclusion of such steps because nowhere in the disclosure has Applicant discussed **consisting essentially of** in the context of the claimed method. Therefore, the rejection under 35 U.S.C. 112, first paragraph, New Matter is proper and maintained.

Appellants' argue "consisting essentially of" language modifies the composition of the daily dosage that is administered to an Alzheimer's patient, rather than any "step" of the recited method.

Examiner does not agree Applicant was not in possession of consisting essentially of language at the time the application, claimed invention, was filed. “Consisting essentially of” in this instant case is considered new matter. Further, Appellants' attention is directed to claim 1, line 1, where the method comprising of….renders the claims with open language. Appellants' arguments have been considered but are not persuasive. Appellants' attention is directed to claim 1, line 1, wherein the method comprising administering a daily dosage….. Appellants are reminded that the claim language is comprising language the transitional term

"comprising", which is synonymous with "including," "containing," or "characterized by," is inclusive or open-ended and does not exclude additional, unrecited elements or method steps. See, e.g., >*Invitrogen Corp. v. Biocrest Mfg., L.P.*, 327 F.3d 1364, 1368, 66 USPQ2d 1631, 1634 (Fed. Cir. 2003) ("The transition 'comprising' in a method claim indicates that the claim is open-ended and allows for additional steps.");< *Genentech, Inc. v. Chiron Corp.*, 112 F.3d 495, 501, 42 USPQ2d 1608, 1613 (Fed. Cir. 1997) ("Comprising" is a term of art used in claim language which means that the named elements are essential, but other elements may be added and still form a construct within the scope of the claim.); *Moleculon Research Corp. v. CBS, Inc.*, 793 F.2d 1261, 229 USPQ 805 (Fed. Cir. 1986); *In re Baxter*, 656 F.2d 679, 686, 210 USPQ 795, 803 (CCPA 1981); *Ex parte Davis*, 80 USPQ 448, 450 (Bd. App. 1948) ("comprising" leaves "the claim open for the inclusion of unspecified ingredients even in major amounts").

Appellants argue that the rejection submitted under the 35 U.S.C. § 103 based upon Laruelle et al. '387, Sandyk '846 and Castillo et al. '994 is improper and should be reversed. Appellant has provided it's own interpretation of the references separately as incorporated here: Laruelle et al. '387 discloses pharmaceutical compositions based upon 5-hydroxytryptophan (5- HTP) and derivatives of 5-hydroxytryptophan, in combination with a nitrogenous heterocyclic compound selected from a group that includes inosine and hypoxanthine (see abstract and column 1, line 60 to column 2, line 16). According to Laruelle et al. '387, the combination of 5-HTP and derivatives of purine, pyrimidine or pyridine bases provide novel pharmaceutical compositions capable of correcting deficiencies of serotonin metabolism: The present invention

provides novel pharmaceutical compositions capable of correcting the deficiencies of serotonin metabolism which are characterized in that they comprise an association of 5- HTP or a derivative thereof with derivatives of purine, pyrimidine, or pyridine bases, or with a combination of derivatives of these bases. The applicants have in fact observed that the combination of 5- HTP with a purine, pyridine, or pyrimidine heterocyclic base enables the cerebral levels of 5-HTP, serotonin and 5-hydroxyindolacetic acid (5-HIAA), which is the principal metabolite of serotonin, to be considerably increased. (colunm 3, lines 17-29; emphasis added) The disclosed pharmaceutical compositions of Laruelle et al. '387 must have at least 5 percent 5-HTP that is chemically associated with the nitrogenous heterocyclic base (see colunm 3, lines 38-46). The 5-HTP-containing pham~aceutical compositions disclosed by Laruelle et al. '387 are said to triple blood levels of 5-HTP and 5-hydroxyindolacetic acid (5- HIAA), the principal metabolite of serotonin (column 4, lines 1-6). Laruelle et al. '387 discloses several specific examples of pharmaceutical compositions which were the subject of a pharmacological study. As set forth in colunms 5-9, all of the studied compositions included significant amounts of 5-HTP. It is clear from the teachings of Laruelle et al. '387 that 5-HTP must be present in significant amounts in the disclosed pharmaceutical compositions, and represents a required active ingredient of the compositions that substantially affects serotonin levels when administered to patients. In contrast, the dosage composition of the presently claimed method excludes the use of the levels of 5-HTP taught by Laruelle et al. '387 by reciting that the daily dosage administered to the Alzheimer's patient consists essentially of from 100 mg to less than

1,000 mg of hypoxanthine, xanthine and/or inosine to a patient. The "consisting essentially of" language excludes additional ingredients that would affect the basic and novel characteristics of the claimed daily dosage. Laruelle et al. '387 teaches that 5-HTP is a required active ingredient of the disclosed pharmaceutical compositions, and must be present in order to affect serotonin levels in patients. Laruelle et al. '387 therefore establishes that 5-HTP affects the basic and novel characteristics of the disclosed composition in that 5-HTP is the active ingredient that controls the serotonin levels in patients. It is clear to those skilled in the art that the elimination of the such a combination would not read on the presently claimed method of treating all Alzheimer's patient by administering a daily dosage consisting essentially of the recited amounts of hypoxanthine, xanthine and/or inosine to the patient.

Appellants' arguments have been considered but are not persuasive. Appellants' attention is directed to claim 1, line 1, wherein the method comprising administering a daily dosage….. Appellants are reminded that the claim language is comprising language the transitional term "comprising", which is synonymous with "including," "containing," or "characterized by," is inclusive or open-ended and does not exclude additional, unrecited elements or method steps. See, e.g., >*Invitrogen Corp. v. Biocrest Mfg., L.P.*, 327 F.3d 1364, 1368, 66 USPQ2d 1631, 1634 (Fed. Cir. 2003) ("The transition 'comprising' in a method claim indicates that the claim is open-ended and allows for additional steps.");< *Genentech, Inc. v. Chiron Corp.*, 112 F.3d 495, 501, 42 USPQ2d 1608, 1613 (Fed. Cir. 1997) ("Comprising" is a term of art used in claim language which means that the named elements are essential, but other elements may

be added and still form a construct within the scope of the claim.); *Moleculon Research Corp. v. CBS, Inc.*, 793 F.2d 1261, 229 USPQ 805 (Fed. Cir. 1986); *In re Baxter*, 656 F.2d 679, 686, 210 USPQ 795, 803 (CCPA 1981); *Ex parte Davis*, 80 USPQ 448, 450 (Bd. App. 1948) ("comprising" leaves "the claim open for the inclusion of unspecified ingredients even in major amounts"). Further, Appellants are reminded that this is an obviousness rejection not anticipatory rejection. Laruelle et al. disclose a pharmaceutical composition suitable for increasing cerebral serotonin concentration, comprising a serotonin precursor and inosine and hypoxanthine (see abstract). Treatment consists of administering to a mammal having a lower than normal cerebral serotonin level an amount of a pharmaceutical composition of the present invention effective to increase the cerebral serotonin level. Daily dosages of 1 to 100 mg/kg are preferred (see col. 5, lines 8-22).

Sandyk teaches a method of treating neurological and mental disorders which are associated with and/or related pathogenetically to deficient serotonin neurotransmission (see abstract). Treatments of neurological and mental disorders which are associated with pathogenetically to deficient serotonin are Alzheimer's disease and Parkinson's disease. Neurological and mental disorders are treated by administering to such humans in need thereof an effective amount of a composition which increases serotonin transmission (col. 7, lines 44-50).

Castillo et al. teach that the invention relates to compositions and methods for treating Alzheimer's Disease and other amyloidoses and cognitive and mental effects thereof; more particularly, it relates to herbal compositions for intervention in

Alzheimer's disease and other amyloidoses and for remedies to cognitive and mental effects thereof (col. 1, lines 12-17). The pharmaceutical agent is selected from polyphenols and plants sterols (see col. 8, lines 13-16). Castillo et al. further discloses that the composition of the invention will have enhanced function when function when taken together with one or more of the following antioxidants such as vitamin C or vitamin E (see col. 19, lines 62-65).

An ordinary person skill in the art can very clearly take the teachings from Laruelle et al. along with Sandyk and in combination with Castillo et al. provide a method of treating Alzheimer disease. The mentioned references have provided a detailed blueprint for a method of treating Alzheimer disease comprising a formulation of hypoxanthine, xanthine, and/or inosine that further comprises antioxidants such as vitamin C or vitamin E and polyphenol, and the steps of which are routine to one of ordinary skill in the art.

Appellants are further reminded that the obviousness rejection is not an anticipation rejection. Laruelle et al. clearly teach a pharmaceutical composition suitable for increasing cerebral serotonin concentration, comprising a serotonin precursor and inosine and hypoxanthine (see abstract). Treatment consists of administering to a mammal having a lower than normal cerebral serotonin level an amount of a pharmaceutical composition of the present invention effective to increase the cerebral serotonin level. Daily dosages of 1 to 100 mg/kg are preferred (see col. 5, lines 8-22) and Sandyk teaches a method of treating neurological and mental disorders which are associated with and/or related pathogenetically to deficient serotonin

neurotransmission (see abstract). Treatment of neurological and mental disorders which are associated with pathogenetically to deficient serotonin are Alzheimer's disease and Parkinson's disease. Neurological and mental disorders are treated by administering to such humans in need thereof an effective amount of a composition which increases serotonin transmission (col. 7, lines 44-50). In obviousness rejection a combination of references is used, and the references are relied upon in combination and are not meant to be considered separately as in a vacuum. It is the combination of all of the cited and relied upon references that make up the state of the art with regard to the claimed invention. Appellants' claimed invention fails to patentably distinguish over the state of the art represented by the combination of the cited references. *In re Young*, 403 F.2d 754, 159 USPQ 725(CCPA 1968); *In re Keller 642 F.2d 413, 208 USPQ 871 (CCPA 1981).*

Moreover, it is noted that rejections under 35 U.S.C. 103(a) are based on combinations of references, where the secondary references are cited to reconcile the deficiencies of the primary reference with the knowledge generally available to one ordinary skill in the art to show that the differences between Appellants' invention and the prior art are such that they would have been modifications that were *prima facie* obvious to the skilled artisan. It is noted that the claimed invention is not required to be expressly suggested in its entirety by any one or all of the references cited under 35 U.S.C. 103(a). Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

Appellants' remarks and arguments have been fully and carefully considered in their entirety, but fail to be persuasive.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/Zohreh Vakili/

Patent Examiner, Art Unit 1614

Conferees:

/Ardin Marschel/

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/Frederick Krass/

Supervisory Patent Examiner, Art Unit 1612